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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HAYES, KRISTEN C

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,713	Applicant(s) FULLAM ET AL.	
	Examiner KRISTEN C. HAYES	Art Unit 3643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 21-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. Claims 21 and 29 recite the limitation of the substance produced by the cells being extracellular. The examiner is unable to locate this limitation in the original disclosure of the invention. The specification seems to indicate the substance is produced by the cells, but it does not seem to indicate the substance is extracellular.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 22, 23 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 22, 23 and 29 recite the limitation "said substance". There is insufficient antecedent basis for this limitation in the claim. This limitation should be changed to "said extracellular substance"

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 21, 25 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Kolehmainen GB 2001434.

9. Regarding claim 21, Kolehmainen discloses a method of testing milk from a mammal for a presence of an infection in the mammal, the method comprising introducing a liquid sample (Kolehmainen, page 1: line 65) of the milk and a reagent (Kolehmainen, page 1: lines 69-70, lines 124-128) into a reaction chamber (6), said reagent having a light-amplifying compound therein; reacting said light-amplifying compound with an extracellular substance produced by cells of the mammal in response to the infection (Kolehmainen, page 1: lines 69-81); measuring immediately emitted light from a reaction between the light-amplifying compound and the substance produced by the cells (Kolehmainen, page 1: lines 77-78).

10. Regarding claim 25, Kolehmainen further discloses measuring the intensity for a maximum of five minutes after the step of introducing (Kolehmainen, page 1: lines 109-112).

11. Regarding claim 29, Kolehmainen discloses a method of testing milk from a mammal for a presence of an infection in the mammal, the method comprising introducing a liquid sample of the milk (Kolehmainen, page 1: line 65) and a reagent (Kolehmainen, page 1: lines 69-70, 124-128) into a reaction chamber (6), said reagent having a light-amplifying compound therein; reacting said light-amplifying compound with an extracellular substance produced by cells of the mammal in response to the infection, the substance being produced before the step of

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introducing the sample and the reagent (if the milk was infected, the cells would inherently produce the extracellular substance, as indicated by the applicant on page 3 lines 28-29 of the instant specification); and detecting an immediate peak of emitted light intensity from a reaction between the light-amplifying compound and the substance produced by cells (Kolehmainen, page 1: lines 77-78).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kolehmainen GB 2001434 in view of Knight EP 0489602.

14. Regarding claims 22 and 23, Kolehmainen discloses the device of claim 21. Not disclosed is the substance being produced by phagocytic leukocytes. Knight teaches the substance being produced by phagocytic leukocytes when they phagocytose bacteria. Knight discloses an alternative substance that is responsive to light and can be used to determine infection. It would have been obvious to one of ordinary skill in the art at the time of the invention to make the substance of Kolehmainen phagocytic leukocytes when they phagocytose bacteria as phagocytic leukocytes when they phagocytose bacteria could provide a more accurate reading.

15. Regarding claim 24, Kolehmainen in view of Knight further discloses the light-amplifying compound reacting with reactive oxygen so as to emit light (Kolehmainen, page 1: line 128).

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16. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kolehmainen GB 2001434 in view of Aerojet GB 1315467.

17. Regarding claim 26, Kolehmainen further discloses a fluid-tight and light-tight (7, 11) reaction chamber of variable capacity (10). Not disclosed are a first inlet port connected to a milk line, a second inlet port connected to a supply of reagent or increasing the capacity of the reaction chamber so as to draw the milk and reagent into the reaction chamber. Aerojet further discloses connecting a first inlet port (12) of a generally fluid and light tight reaction chamber (26) of variable capacity to a milk sample (11), connecting a second inlet port (14) of the reaction chamber to a supply (13) of reagent and increasing capacity of the chamber (by way of 23) (Aerojet, page 3: lines 5-9) in order to draw milk and reagent into the chamber. Not disclosed is the first inlet port being connected to a milk line in an automated milking system. However, Aerojet discloses maintaining a continuous flow within the system between the sensor and samples (Aerojet, page 3: lines 10-14). It would have been obvious to one of ordinary skill in the art at the time of the invention connect a first inlet port of the reacting chamber to a milk line, connect a second inlet port to a supply of reagent and to draw the milk and reagent into the reaction chamber as to automate the system of Kolehmainen and to connect the first inlet port of Aerojet to a milk line in an automated milking system so to provide continuous flow to the sensor, as suggested by Aerojet.

18. Regarding claim 27, Kolehmainen in view of Aerojet discloses the device of claim 26. Aerojet further discloses controlling an electrically-actuated operating valve (16) to regulate proportion of reagent and sample drawn into the reaction chamber (Aerojet, page 1: lines 79-85). Not disclosed is a plurality of valves with the valves provided in inlet ports. A plurality of valves, with a valve in each inlet port would provide the predictable result of allowing the amount of sample or reagent to be controlled individually with the user able to control the ratio of milk to

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sample. It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the device Kolehmainen with electrically-actuated operating valves as to accurately control the amount of sample and reagent feed into the reaction chamber and to modify the device of Aerojet so that there was a plurality of valves, with a valve in each inlet port, as discussed above.

19. Regarding claim 28, Kolehmainen as modified by Aerojet further discloses moving a piston (Kolehmainen, (10)) in the reaction chamber.

Response to Arguments

20. Applicant's arguments filed 03/19/2009 have been fully considered but they are not persuasive.

21. During the interview held 03/12/2009 it was clarified that the method was intended to be an in-line test that was performed immediately when the milk was taken. The applicant argues that Kolehmainen teaches a storage period of the milk, which the reference does. However, the applicant claims that the measurement is taken immediately after the compound and the extracellular substance are combined, not that the measurement is taken immediately after the milk sample is gathered.

22. The applicant has also stated that the substance of Kolehmainen is from the inside of the cell which bursts when the NRS reagent is combined with the milk. However, no evidence has been provided (or passage pointed out in the prior art of Kolehmainen) to support this. The applicant's attention is also directed towards a passage in Kolehmainen which discloses the use of other luminescent systems besides NRS such as luminol (Kolehmainen: page 1: lines 127-128) which the applicant has disclosed as reacting with oxygen which is produced extracellularly in response to infection in the animal.

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23. Applicant is encouraged to contact the examiner to clarify issues which would advance prosecution.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. HAYES whose telephone number is (571)270-3093. The examiner can normally be reached on Monday-Thursday, 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Poon can be reached on (571)272-6891. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCH
21 May 2009

Peter Poon
Examiner
Art Unit 3643

/Peter M. Poon/
Supervisory Patent Examiner, Art Unit 3643